REMARKS

In the present Amendment, claim 1 has been amended to incorporate the subject matter of claim 7 and to recite that the infusion preparation comprises about 0.1 mg to about 10 mg of (2R)-2-propyloctanoic acid or a salt thereof per mL and about 1.2 to about 3.5 equivalents of a basic metal ion based on 1 equivalent of (2R)-2-propyloctanoic acid or a salt thereof, and that the infusion preparation comprises at least a metal salt of phosphoric acid. Support for the amendments is found, for example, at page 12, lines 16-18 and in the Examples of the specification and in the Declaration under 37 C.F.R. § 1.132 filed January 26, 2010. Claim 7 has been cancelled accordingly. Claims 3 and 8 have been cancelled without prejudice or disclaimer. Claims 5, 6 and 10 have been amended in view of the amendments to claim 1. Claim 9 has been amended to improve its form and to depend from claim 1. Claim 11 has been amended to depend from claim 1. New claims 17-20 have been added. Claims 17-20 narrow the scope of claim 1. No new matter has been added, and entry of the Amendment is respectfully requested.

Upon entry of the Amendment, claims 1, 5, 6, 9-12, 14, 15 and 17-20 will be pending, of which claims 14 and 15 are withdrawn from consideration.

Response to § 103(a) Rejection

Claims 1, 3, and 5-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Toda *et al.* (US 6,608,221, "Toda") in view of Black (US 6,043,223) or Sakanaka *et al.* (US 2003/010407, "Sakanaka").

This rejection should be withdrawn because Toda, Black and Sakanaka do not disclose or render obvious the present invention, either alone or in combination.

In the Amendment under 37 C.F.R. § 1.111 filed January 26, 2010, Applicants submitted a Declaration Under 37 C.F.R. § 1.132 executed by Mr. Seiichi Tanikawa to show that the present invention provides unexpectedly superior results, i.e., (1) the infusion preparation of the present invention makes a water-insoluble (2R)-2-propyloctanoic acid soluble in water and does not require the operation such as dissolution or dilution at the time of use; (2) even if the pH changes as a result of mixing with other pharmaceutical agent, neither clouding nor precipitation occurs; and (3) the stability is excellent. Applicants then explained that, in view of the unexpectedly superior and remarkable effects of the present claimed invention, Toda in view of Black or Sakanaka do not render the present claimed invention obvious.

In response, the Examiner states that although Applicants were able to demonstrate unexpected results (i.e. soluble and stable solutions) for the infusion preparation comprising (2R)-2-propyloctanoic acid for a narrow set of conditions, the data provided by Applicant in the specification and in the 1.132 declaration is not commensurate in scope with the claims.

To address the Examiner's concern, claim 1 has been amended to recite that the infusion preparation comprises about 0.1 mg to about 10 mg of (2R)-2-propyloctanoic acid or a salt thereof per mL and about 1.2 to about 3.5 equivalents of a basic metal ion based on 1 equivalent of (2R)-2-propyloctanoic acid or a salt thereof, and that the infusion preparation comprises at least a metal salt of phosphoric acid.

The basic metal ion salts utilized in the Examples of the specification are trisodium phosphate·dodecahydrate and disodium hydrogen phosphate·dodecahydrate. Disodium monohydrogen phosphate·dodecahydrate is employed in the Declaration. The concentration of (2R)-2-propyloctanoic acid in the Declaration is from 0.1 mg/mL to 10 mg/mL.

With regard to equivalent, all equivalent described in Examples is 2.6 equivalent. Further, equivalent ratio is described in the samples in Declaration as "Appropriate amount of sodium hydroxide was added thereto to adjust the pH to be 8.4 to 9.0." With regard to the samples in Declaration, the samples were produced by mixing (2R)-2-propyloctanoic acid, 1.7 equivalent of disodium monohydrogen phosphate and appropriate amount of sodium hydroxide. It is known by experience that about 1 equivalent of sodium hydroxide has to be added (1.7 equivalent of disodium monohydrogen phosphate + 1 equivalent of sodium hydroxide = 2.7 equivalents) when pH is adjusted to be 8.4 to 9.0 under the condition. The equivalent ratio of 1.2 to 3.5 equivalents is disclosed as preferable equivalent ratio at page 12, lines 16-18 of the specification. Additionally, the amount of added sodium hydroxide can be defined automatically by reciting the definition of pH.

Therefore, the present claims as amended are commensurate in scope with the data provided by Applicant in the specification and in the 1.132 Declaration.

Additionally, Applicants would like to clarify the difference between equivalent ratio and weight ratio. As described in the specification, "equivalent" in the present application is the supplied amount of basic metal ions. Namely, when equivalent is considered based on 1 mole of (2R)-2-propyloctanoic acid, 1 mol of sodium hydroxide is 1 equivalent; 0.5 mol of disodium

monohydrogen phosphate is 1 equivalent (since it has two Na); and about 0.34 mol of trisodium phosphate is 1 equivalent (since it has three Na).

In view of the above, reconsideration and withdrawal of the §103(a) rejection based on Toda in view of Black or Sakanaka are respectfully requested.

New claims 17-20 are patentable over the cited references for at least the same reasons that claims 1, 5, 6 and 9-12 are patentable over the cited references, as discussed above.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Hui Chen Wauters

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

65565
CUSTOMER NUMBER

Hui C. Wauters
Registration No. 57,426
for Sunhee Lee
Registration No. 53,892

Date: July 29, 2010

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Masao SUDOH, et al.

Docket No: Q94153

Appln. No.: 10/574,476

Group Art Unit: 1612

Confirmation No.: 2354

Examiner: Marcos L SZNAIDMAN

Filed: October 5, 2006

For: INFUSION PREPARATION CONTAINING (2R)-2-PROPYLOCTANOIC ACID AS THE ACTIVE INGREDIENT

EXCESS CLAIM FEE PAYMENT LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

An Amendment Under 37 C.F.R. § 1.114(c) is attached hereto for concurrent filing in the above-identified application. The resulting excess claim fee has been calculated as shown below:

	After Amendment		Highest No. Previously Paid For					
All Claims	13	-	20	=		X	$52.00	= $.00
Independent	5	-	3	=	2	X	$220.00	= $440.00
					TOTAL			= **$440.00**

The USPTO is directed and authorized to charge the statutory fee of $440.00 and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880.

Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Hui Chen Wauters

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

65565
CUSTOMER NUMBER

Date: July 29, 2010

Hui C. Wauters
Registration No. 57,426
for Sunhee Lee
Registration No. 53,892